codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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CX 4/60.2 **CL 2005/43-RVDF**
September 2005

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **REQUEST FOR COMMENTS/INFORMATION ON PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION**

DEADLINE: **28 February 2006**

COMMENTS:

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BACKGROUND

1. The Codex Committee on Residues of Veterinary Drugs in Foods at its 15th Session (October 2004) agreed to convene the *ad hoc* Working Group on Priorities prior to its next Session under the Chairmanship of Australia to consider proposals for compounds to be evaluated or re-evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (ALINORM 05/28/31, para. 177). The priority list for the establishment of MRLVDs by the CCRVDF (ALINORM 05/28/31, Appendix IX) was approved by the 28th Session of the Codex Alimentarius Commission (ALINORM 05/28/41, Appendix VIII) as new work.

2. The Committee also noted that the *ad hoc* Working Group had discussed the recommendations of the Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL related to the establishment of priorities.

3. The Committee agreed to establish a Working Group coordinated by the Delegation of the European Community in order to develop recommendations on how to deal with compounds for which an ADI or MRL could not be set.

4. The Committee agreed that the new Working Group would prepare a paper for consideration by the Committee by July 2005. The new Working Group would report back to the 16th Session of the Committee through the *ad hoc* Working Group on Priorities (ALINORM 05/28/31, paras 172-176).

REQUEST FOR COMMENTS/INFORMATION

5. Governments and interested organizations are invited, as directed above, to make proposals for veterinary drugs to be added to the priority lists for subsequent recommendation to JECFA for evaluation or re-evaluation **not later than 28 February 2006**.

6. Annex 1 to this document outlines the selection criteria established by the CCRVDF which should be borne in mind when submitting proposals.

7. Annex 2 is the form on which information is to be provided. Only brief details are required and the form can be retyped if more space is needed under any one heading provided that the general format is maintained. In preparing proposals, member governments should consult with the manufacturer(s) about the existence of appropriate toxicology and residue data and confirm that the manufacturer(s) would be willing to submit data to JECFA and in what year. Proposals submitted should also be listed in priority order.

8. Annex 3 outlines the toxicology and residues studies that are relevant for JECFA consideration. In some cases it is appreciated that not all studies might be available.

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ANNEX 1

CRITERIA FOR THE INCLUSION IN, OR EXCLUSION FROM, SUBSTANCES IN THE PRIORITY LIST

In order to be placed on the CCRVDF priority list for the development of a maximum residue limit, the candidate veterinary drug, when used in accordance with good veterinary practices, should meet some, but not necessarily all, of the following criteria:

1) Use of the drug will have potential to cause public health and/or trade problems;

2) Drug available as commercial product, and;

3) Commitment that a dossier will be available.

ANNEX 2

FORMAT FOR PRESENTATION OF INFORMATION ON COMPOUNDS TO BE INCLUDED INTO THE CCRVDF PRIORITY LIST

1. Proposal for Inclusion Submitted by (Country):

2. Drug Name:

3. Trade Names:

4. Chemical Names:

5. Names and Addresses of Basic Producers:

6. Justification for Use:

7. Veterinary Use Pattern:

8. Countries Where Drug is Registered:

9. National Maximum Residue Levels:

10. Commodities for Which the Need for Establishing Codex MRLs Is Required:

11. List of Data (Toxicology, Metabolism, Residue) Available:

12. Date Data Could be Submitted to JECFA:

ANNEX 3

DATA REQUIREMENTS FOR EVALUATION BY JECFA

1. Identify
   - i. Chemical name
   - ii. Synonyms
   - iii. Structural formula
   - iv. Molecular formula
   - v. Other information on identity:
     - molecular weight
     - specification of technical material
     - degree of purity
     - qualitative and quantitative composition of impurities
2. Data relevant to the toxicological evaluation of the substance, including:
   - i. Pharmacokinetic, metabolic and pharmacodynamic studies in experimental and food-producing animals, and in humans when available;
   - ii. Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity and developmental toxicity studies in experimental animals and genotoxicity studies;
   - iii. Special studies designed to investigate specific effects, such as those on mechanisms of toxicity, no-hormonal-effect levels, immune responses or macromolecular binding;
   - iv. For compounds with antimicrobial activity, studies designed to evaluate the possibility that the compound might have an adverse effect on the microbial ecology of the human intestinal tract, and;
   - v. Studies providing relevant data on the use of and exposure to the drug by humans, including studies of effects observed after occupational exposure and epidemiological data following clinical use in humans.
3. Data relevant to the evaluation of residues in food-producing animals, including:
   - i. Chemical identity and properties of the drug;
   - ii. Its use and dosage range;
   - iii. Ss for the toxicological evaluation, pharmacokinetic and metabolic studies in experimental animals, target animals, and humans when available;
   - iv. Residue-depletion studies with radiolabelled drug in target animals from zero withdrawal time to periods extending beyond the recommended withdrawal time (these studies should provide information on total residues, including free and bound residues, and major residue components to permit selection of a marker residue and target tissue);
   - v. Residue-depletion studies with unlabelled drug for the analysis of marker residue in target animals and in eggs, milk and honey (these should include studies with appropriate formulations, routes of application and species, at doses up to the maximum recommended);
   - vi. A description of the analytical procedures used by the sponsor for the detection and determination of parent drug residues with information on validation and performance characteristics, and;
   - vii. A review of routine analytical methods that may be used by regulatory authorities for the detection of residues in target tissue.